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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,984	07/29/2003	Jurgen G. Schmidt	S-100,648	9223

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EXAMINER	
EPPERSON, JON D	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 04/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/629,984	SCHMIDT ET AL.	
	Examiner	Art Unit	
	Jon D. Epperson	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-16* is/are pending in the application.

4a) Of the above claim(s) *5,6,9 and 11-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,7,8 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

1. The Response filed February 9, 2006 is acknowledged.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior office action.

Status of the Claims

3. Claims 1-16 were pending. Claim 2 was canceled and claims 1, 3 and 4 were amended. Therefore, claims 1 and 3-16 are currently pending.

4. Claims 5, 6, 9, 11-16 are drawn to non-elected species and/or inventions and thus these claims remain withdrawn from further consideration by the examiner, 37 CFR 1.142(b), there being no allowable generic claim.

5. Therefore, claims 1, 3, 4, 7, 8 and 10 are examined on the merits in this action.

Withdrawn Objections/Rejections

6. The rejection under 112, second paragraph is withdrawn in view of Applicants' arguments and/or amendments. All other rejections are maintained and the arguments are addressed below.

Outstanding Objections and/or Rejections

Claim Rejections - 35 USC § 112, first paragraph

7. Claims 1, 3, 4, 7, 8 and 10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

To satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the claimed invention (e.g., see *In re Edwards*, 568 F.2d 1349, 1351-52, 196 USPQ 465, 467 (CCPA 1978)). Applicants' claims are directed to a broad genus of compositions having a trifunctional chemical moiety covalently attached thereto at a resin attachment site, said trifunctional chemical moiety including hydrophobic anchoring groups thereon (e.g., see independent claim 1), which represents enormous scope because Applicants do not place any limitations on the number of atoms, types of atoms or the way in which said atoms can be connected together to form such a compound and/or composition. Thus, virtually an infinite number of possibilities would be included in Applicants' claimed scope encompassing virtually every known class and subclass of compounds. In addition, Applicants' more narrowly drawn sub-genera do not alleviate these deficiencies. For example, the specification does not define the term "derivative" as used in dependent claims 3 and 4. The specification and claims do not place any limit on the number of substitutions, deletions, insertions and/or additions that may be used to

modify the amino acid structure to form said derivatives. Thus, the scope still includes an enormous number of structural variants.

In contrast, Applicants' specification provides only one working example of the claimed invention (e.g., see specification, pages 17-20; see also figures 2 and 5). Applicants disclose the condensation of para-nitrophenyl carbonate Wang resin with a lysine trifunctional group containing a $(C_{18}H_{37})_2$ anchoring group (e.g., see Examples 1 and 2; see also figure 5). In addition, Applicants further disclose that the Wang immobilized lysine can be used in peptide synthesis to create peptides like "VPPYFTLMYGGGGK" (e.g., see Example 2).

Applicants are referred to the discussion in *University of California v. Eli Lilly and Co.* (U.S. Court of Appeals Federal Circuit (CAFC) 43 USPQ2d 1398 7/22/1997 Decided July 22, 1997; No. 96-1175) regarding adequate disclosure. For adequate disclosure, like enablement, requires representative examples, which provide reasonable assurance to one skilled in the art that the compounds falling within the scope both possess the alleged utility and additionally demonstrate that *applicant had possession of the full scope of the claimed invention.* See *In re Riat* (CCPA 1964) 327 F2d 685, 140 USPQ 471; *In re Barr* (CCPA 1971) 444 F 2d 349, 151 USPQ 724 (for enablement) and *University of California v. Eli Lilly and Co* cited above (for disclosure). The more unpredictable the art the greater the showing required (e.g. by "representative examples") for both enablement and adequate disclosure. In addition, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus (e.g., see MPEP § 2163.05).

Here, Applicants have only provided one working example of the claimed invention (i.e., a polystyrene immobilized lysine that is used in peptide synthesis). Thus, a person of skill in the art would not believe that Applicants were in possession of a genus that encompasses virtually an infinite number of compounds and/or compositions encompassing every class and subclass. For example, while solid phase synthesis of various compounds was known at the time of filing (i.e., resin containing compositions), such synthesis was not sufficiently routine or predictable at the time of filing, to permit one of skill in the art to devise strategies for the use of any solid support containing a trifunctional moiety having any active sites protected in any way. This type of synthesis requires high efficiently in the coupling steps and protection/deprotections and is further complicated by carryover, cross-reactions and/or unintentional cleavage, all of which are acknowledged issues in the art; each must be dealt with in the optimization of a solid phase synthesis scheme. A review article published by Janda in late 1994, discusses these issues (Janda, K. D. "Tagged versus untagged libraries: Methods for the generation and screening of combinatorial chemical libraries" *Proc. Natl. Acad. Sci.* **November 1994**, Vol. 91 pp. 10779-10785,. See especially page 10782-10785). Orthogonal protection of different reactive groups (active sites) was known in the art to be necessary for efficient solid phase synthesis (see Janda Figure 5, page 10783). The art of solid phase synthesis is known to be difficult to optimize, especially when multiple compounds are present (ass discussed in Janda, set forth supra).

Furthermore, while Applicants have demonstrated that a para-nitrophenyl carbonate Wang resin can be used with the present invention, this would not allow a

person of skill in the art to conclude that any resin could be employed. For example, Yan et al states, "A common problem in SPOS [solid phase organic synthesis] practice is that reaction conditions can not simply be transferred from one kind of support to another. A set of reaction conditions may work well for polystyrene resins, but may fail completely for pin- or PS-PEG resin-based synthesis" (see Yan, B.; Gremlich, H. –U. "Role of Fourier Transform infrared spectroscopy in the rehearsal phase of combinatorial chemistry: a thin-layer chromatography equivalent for on-support monitoring of solid-phase organic synthesis" *J. Chromatogr. B: Biomed. Sci. Applic.* **1999**, 725, 91-102, especially page 97 paragraph 2).

Thus, applicants have not demonstrated in "full, clear, concise, and exact terms" that they are in possession of the claimed invention. The specification and claims do not provide any guidance as to what changes should be made to extend Applicants' one example to the infinite number of possibilities that are currently being claimed. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variable, Applicants' single example is insufficient to describe the enormous genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus. *See Fiers v. Revel,* 984 F.2d 1164, 1171 (Fed. Cir. 1993); *See also Brenner v. Manso*n, 383 U.S. 519, 535–36, 148 USPQ 689, 696 (1966) (noting, "A patent is not a hunting license. It is not a reward for the

search, but compensation for its successful conclusion.").

Response

8. Applicant's arguments directed to the above written description rejection were fully considered (and are incorporated in their entirety herein by reference) but were not deemed persuasive for the following reasons. Please note that the above rejection has been modified from it original version to more clearly address applicants' newly amended and/or added claims and/or arguments.

[1] Applicants argue that the specification provides support for the terms used in the claims including "trifunctional" and "derivative" (e.g., see 10/21/05 Response, page 7, last two paragraphs).

[2] Applicants argue, "[a]lthough the claims are drawn to numerous structural variants, the chemistries associated with creating embodiments of the compositions claimed are well known, routine, and well within the scope of the ordinarily skilled artisan ... there is no need for multiple examples to communicate to those skilled in the art that the applicant is in possession of the full scope of the invention. The specification need not contain any example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without undue amount of experimentation ... the invention is disclose in a manner that enables one skilled in the art to make the claimed compositions without undue experimentation, and applicants should not be burdened with a requirement for multiple examples" and cite *In re Borkowski* in support of this argument (e.g., see 10/21/05 Response, page 8, last paragraph).

This is not found persuasive for the following reasons:

[1] The Examiner respectfully disagrees. The language of the specification should describe the claimed invention so that one skilled in the art can recognize what is claimed. A description of a compound in terms of its function fails to distinguish the compound from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. *University of California v. Eli Lilly and Co.* (U.S. Court of Appeals Federal Circuit (CAFC) 43 USPQ2d 1398 7/22/1997 Decided July 22, 1997; No. 96-1175). Applicants admit that the present claims encompass "numerous structural variants" (e.g., see 10/21/05 Response, page 8, last paragraph), which can only be distinguished by their function. Thus, a person of skill in the art would not be able to recognize what is currently being claimed. Furthermore, the cited passages only provide "examples" of what is encompassed, not a definition.

[2] First, the Examiner notes that the enablement requirement (i.e., whether or not "undue experimentation" is required) is separate and distinct from the written description requirement of § 112, first paragraph. See *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1117. A specification may enable one skilled in the art to make and use an invention and yet still not describe it. Id. at 1561, 19 USPQ2d at 1115. Thus, *In re Borkowski*, a case that involved whether or not a process could be practiced without "undue experimentation" (see Applicants arguments above) for producing oxygenated hydrocarbons by reacting hydrocarbons with ferric chloride in vapor phase and hydrolyzing the resulting chlorohydrocarbon is not applicable. That is, the issue in *Borkowski* was enablement, not written description.

Second, the appropriate standard for the written description requirement was set forth, for

example, in the *University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The claims in *Lilly* were directed generically to vertebrate or mammalian insulin cDNAs. See 119 F.3d at 1567, 43 USPQ2d at 1405. The court held that a structural description of a rat cDNA was not an adequate description of these broader classes of cDNAs, because a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." Id. (bracketed material in original). The *Lilly* court explained that a generic statement such as . . . 'mammalian insulin cDNA,' without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. Id. at 1568, 43 USPQ2d at 1406. Finally, the *Lilly* court held that a genus of cDNAs could be described by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. Id.

The Federal Circuit revisited this issue in *Enzo*. See *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court clarified that a

description of DNA need not, necessarily, disclose its structure. The court adopted the standard that the written description requirement can be met by "show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics . . . i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." Id. at 1324, 63 USPQ2d at 1613 (emphasis omitted, ellipsis and bracketed material in original). In addition, the Court in *Rochester* made clear that these standards are not limited to DNA. (e.g., see *University of Rochester v. G.D. Searle & Co., Inc.* 69 USPQ2d 1886, 1895, "As we held in Lilly, "[a]n adequate written description of a DNA . . . 'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention." 119 F.3d at 1566 (quoting Fiers, 984 F.2d at 1171). For reasons stated above, that requirement applies just as well to non-DNA (or RNA) chemical inventions").

Thus, the instant specification can provide an adequate description of the claimed genus, per *Lilly*, by providing a "precise" definition, such as by structure, formula, or chemical name or, alternatively, describing a "representative number" of species, which constitutes a "substantial" portion of the genus. The instant specification can also provide an adequate description, per *Enzo*, by providing sufficiently detailed, relevant identifying characteristics such as complete or partial structure or functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.

In the instant case, the specification fails both *Lilly* and *Enzo*. With regard to *Lilly*, the specification fails to provide a "precise" definition, such as by structure, formula, or chemical

name. Claim 1's recitation of "trifunctional" chemical moiety and "membrane anchoring" groups and claims 3 and 4's recitation of an amino acid "derivative" fall squarely within the category of compounds defined by function, not structure, which were disparaged by the *Lilly* court. See 119 F.3d at 1568, 43 USPQ2d at 1406 ("A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is."). Furthermore, the claims at bar represent an even more egregious violation of the written description requirement than the cDNAs that were claimed in *Lilly* because the present claims do not even set forth the "function" for the claimed "trifunctional" chemical moieties that might otherwise be used to help characterize these molecules. For example, the trifunctional molecule could encompass a "linking" function (where three different moieties are linked together), an "antibiotic" function (where three different bacteria are inhibited), etc.

Furthermore, Applicants' specification provides only one working example of the claimed invention (e.g., see specification, pages 17-20; see also figures 2 and 5; see also Examples 1 and 2 wherein the condensation of para-nitrophenyl carbonate Wang resin with a lysine trifunctional group containing a $(C_{18}H_{37})_2$ anchoring group), which is not "representative" of a "substantial portion" of a broad genus that includes an infinite number of members. The cited passages in the specification do not remedy this defect because, for example, with regard to the "trifunctional chemical moiety" the specification merely refers to the "example" set forth in figure 1 and some other potential possible functionalities (e.g., page 3 line 17 through page 4 line 5). Thus, the cited passage does not provide any structural features common to all of the "trifunctional" members. Since the specification describes no structural features that are

common to the members of the genus, it necessarily does not describe structural features that "constitute a substantial portion of the genus," per *Lilly*, which would encompass virtually an infinite number of structurally unrelated molecules.

With regard to *Enzo*, the specification fails to set forth any "sufficiently detailed, relevant identifying characteristics" that might otherwise allow Applicants to show that they were in possession of the claimed invention. Applicants do not set forth a structure/activity relationship (e.g., page 3, lines 17 through page 4, line 5 and figure 1 merely provide potential examples of a trifunctional chemical moiety). Applicants' specification also does not provide a partial or complete structure or any other identifying characteristics. Moreover, the Examiner notes hat when there is little to no disclosure in the instant specification of the starting material or conditions under which claimed process can be carried out, this failure cannot be rectified by asserting that all disclosure related to the process is within skill of art. *Genentech Inc. v. Novo Nordisk A/S* (CA FC) 42 USPQ2d 1001 (3/13/1997).

Finally, the Examiner contends that the Board has held on the issue of unpredictability that "... the unpredictability of an art area alone may be enough to create a reasonable doubt as to the accuracy of statements in the specification." *Ex parte Singh*, 17 U.S.P.Q.2d 1714,1716 (B.P.A.I. 1990). Thus, in applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. *In re Soll*, 97 F.2d 623, 624, 38USPQ 189, 191 (CCPA 1938). In the present case, Applicants have failed to address this issue with regard to the Janda and Yan references cited above. That is, contrary to Applicants' assertions, making and using the full scope of the claimed invention is not routine in the art.

Accordingly, the written description rejection cited above is hereby maintained.

9. Claims 1, 3, 4, 7, 8 and 10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling compositions containing a "lysine" trifunctional group bound to a "polystyrene" resin that contains a membrane anchoring group with ~C_{18} carbon chains, does not reasonably provide enablement for any trifunctional group bound to any resin containing any anchoring group. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". Some of these factors may include, but are not limited to:

(1) the breadth of the claims;
(2) the nature of the invention;
(3) the state of the prior art;
(4) the level of one of ordinary skill;
(5) the level of predictability in the art;
(6) the amount of direction provided by the inventor;
(7) the existence of working examples; and
(8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

(1 and 2) The breadth of the claims and the nature of the invention: The claims are drawn to a broad genus because Applicants do not place any limitations on the number of atoms, types of atoms or the way in which said atoms can be connected

together to form such a composition. Thus, virtually an infinite number of possibilities would be included in Applicants' claimed scope encompassing virtually every known class and subclass of compounds. In addition, all of Applicants' more narrowly drawn sub-genera are also not adequately described. For example, term "derivative" as used in dependent claims 3 and 4 could refer to virtually an unlimited number of chemical transformations. The specification and claims do not place any limit on the number of substitutions, deletions, insertions and/or additions that may be used to modify the amino acid structure to form said derivatives. Thus, the scope of even the more narrowly drawn subgenera still include an enormous number of structural variants. Consequently, the nature of the invention cannot be fully determined because the invention has not been defined with particularity.

(3 and 5) The state of the prior art and the level of predictability in the art: While solid phase synthesis of various compounds was known at the time of filing (i.e., resin containing compositions), such synthesis was not sufficiently routine or predictable at the time of filing, to permit one of skill in the art to devise strategies for the use of any solid support containing a trifunctional moiety having any active sites protected in any way. This type of synthesis requires high efficiently in the coupling steps and protection/deprotections and is further complicated by carryover, cross-reactions and/or unintentional cleavage, all of which are acknowledged issues in the art; each must be dealt with in the optimization of a solid phase synthesis scheme. A review article published by Janda in late 1994, discusses these issues (Janda, K. D. "Tagged versus untagged libraries: Methods for the generation and screening of combinatorial chemical

libraries" *Proc. Natl. Acad. Sci.* **November 1994**, Vol. 91 pp. 10779-10785,. See especially page 10782-10785). Orthogonal protection of different reactive groups (active sites) was known in the art to be necessary for efficient solid phase synthesis (see Janda Figure 5, page 10783). The art of solid phase synthesis is known to be difficult to optimize, especially when multiple compounds are present (ass discussed in Janda, set forth supra).

Furthermore, while Applicants have demonstrated that a para-nitrophenyl carbonate Wang resin can be used with the present invention, this would not allow a person of skill in the art to conclude that any resin could be employed. For example, Yan et al states, "A common problem in SPOS [solid phase organic synthesis] practice is that reaction conditions can not simply be transferred from one kind of support to another. A set of reaction conditions may work well for polystyrene resins, but may fail completely for pin- or PS-PEG resin-based synthesis" (see Yan, B.; Gremlich, H. –U. "Role of Fourier Transform infrared spectroscopy in the rehearsal phase of combinatorial chemistry: a thin-layer chromatography equivalent for on-support monitoring of solid-phase organic synthesis" *J. Chromatogr. B: Biomed. Sci. Applic.* **1999**, 725, 91-102, especially page 97 paragraph 2).

(4) The level of one of ordinary skill: The level of skill required would be high, most likely at the Ph.D. level.

(6-7) The amount of direction provided by the inventor and the existence of working examples: Applicants' specification provides only one working example of the claimed invention (e.g., see specification, pages 17-20; see also figures 2 and 5).

Applicants disclose the condensation of para-nitrophenyl carbonate Wang resin with a lysine trifunctional group containing a $(C_{18}H_{37})_2$ anchoring group (e.g., see Examples 1 and 2; see also figure 5). In addition, Applicants further disclose that the Wang immobilized lysine can be used in peptide synthesis to create peptides like "VPPYFTLMYGGGGK" (e.g., see Example 2). In addition, Applicants provide no art-recognized "core" structure that might otherwise allow a person of skill in the art to conclude that the vast majority of molecules that fall within the scope of the claimed invention would elicit a similar biological activity (see Ex parte Bhide 42 USPQ2d 1441). That is, a "trifuncitonal" moiety is not an "art-recognized" core structure that will elicit a predictable response.

(8) The quantity of experimentation needed to make or use the invention base on the content of the disclosure: As a result of the broad and unpredictable nature of the invention and the lack of specific guidance from the specification, the Examiner contends that the quantity of experimentation needed to make and or use the invention would be great. Note that there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and use the invention as broadly as it is claimed. *In re Vaeck*, 947 F.2d 488, 496 & n.23, 20 USPQ2d 1438, 1445 * n.23 (Fed. Cir. 19991). In this case, Applicants have not provided any working examples that would teach this enormous genus that falls within a highly unpredictable art area. Therefore, it is deemed that further research of an unpredictable nature would be necessary to make or use the invention as claimed. Thus, due to the inadequacies of the instant disclosure one of ordinary skill would not have a reasonable expectation of

success and the practice of the full scope of the invention would require undue experimentation.

Response

10. Applicant's arguments directed to the above Enablement rejection were fully considered (and are incorporated in their entirety herein by reference) but were not deemed persuasive for the following reasons. Please note that the above rejection has been modified from it original version to more clearly address applicants' newly amended and/or added claims and/or arguments.

[1] Applicants argue that they have provided sufficient examples citing their own U.S. Patent (No. 6,627,396), which are presumably "representative" of the claimed genus, and further contend that the ability to make such compositions is well within the ordinary level of skill in the art (e.g., see 10/21/05 Response, page 9, middle paragraph).

[2] Applicants argue, "... although the claims are drawn to numerous structural variants, the chemistries associated with creating embodiments of the compositions claims are well known ... solid phase chemistry has been known for decades ... The chemistries needed for modifying the reactive groups of the claimed compositions are well known and predictable (e.g., see 10/21/05 Response, pages 9 and 10).

[3] Applicants again argue that the chemistry used to make the claim composition is well known in the art and that representative examples need not be disclosed when the art is predictable and cite *In re Borkowski* in support of this argument (e.g., see 10/21/05 Response, page 10, last two paragraphs).

This is not found persuasive for the following reasons:

[1] The Examiner respectfully disagrees. Patent No. 6,627,396 merely discloses the same example set forth in the current application (e.g., compare '396, figure 2, to figure 1 of the present application) and, as a result, fails to further support Applicants arguments. In addition, Applicants contentions that the chemistries are well known in the art are wholly unsupported. Finally, the Examiner notes that Applicants failed to address the Janda and Pan references set forth above, which clearly indicate that the art is unpredictable.

[2] Again, Applicants fail to address the Janda and Pan references. Consequently, Wand factors 3 and 5 (see above) have been conceded. Applicants' citation to page 11, line 1 of the specification does not refute in any way the Janda and Pan references. In addition, Applicants admit that the claimed scope is broad (e.g., see 10/21/05 Response, page 9, last paragraph, "... although the claims are drawn to numerous structural variants ...") and, as a result, Wands factors 1 and 2 are conceded. Finally, Applicants do not refute that their specification provides only one working example of the claimed invention (e.g., see specification, pages 17-20; see also figures 2 and 5; see also Examples 1 and 2 wherein the condensation of para-nitrophenyl carbonate Wang resin with a lysine trifunctional group containing a $(C_{18}H_{37})_2$ anchoring group). Thus, Wands factors 6 and 7 also favor a finding of non-enablement.

[3] "It is well settled that patent applicants are not required to disclose every species encompassed by their claims, even in an unpredictable art ... However, there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill in the art how to make and how to use the invention as broadly as it is claimed." In re Vaeck, 947 F.2d 488, 496, 20 USPQ2d 1438, 1445 (Fed. Cir. 1991) (footnote omitted). "The scope of the

claims must be less than or equal to the scope of the enablement. The scope of enablement, in turn, is that which is disclosed in the specification plus the scope of what would be known to one of ordinary skill without undue experimentation." *National Recovery Technols. Inc. v. Magnetic Separation Sys., Inc.*, 166 F.3d 1228, 1232, 49 USPQ2d 1671, 1675-76 (Fed Cir. 1999). In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved. See *In re Fisher*, 57 CCPA 1099,427 F.2d 833,839,166 USPQ 18,24(1970). Additionally, the Board has held on the issue of unpredictability that "... the unpredictability of an art area alone may be enough to create a reasonable doubt as to the accuracy of statements in the specification." *Ex parte Singh*, 17 U.S.P.Q.2d 1714,1716 (B.P.A.I. 1990).

Here, Janda and Pan clearly indicate that the art is unpredictable. For example, Janda indicates that the art of solid phase synthesis is known to be difficult to optimize, especially when multiple compounds are present (see above rejection). Furthermore, Yan et al states that not all solid-phase supports are created equal (e.g., see rejection above, "A common problem in SPOS [solid phase organic synthesis] practice is that reaction conditions can not simply be transferred from one kind of support to another. A set of reaction conditions may work well for polystyrene resins, but may fail completely for pin- or PS-PEG resin-based synthesis"). Thus, the art is unpredictable and Applicants' one example does not provide sufficient guidance to make the infinite number of compounds that are currently claimed.

In addition, Applicants have not provided any utility for the vast number of claimed compounds. For example, in *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d. 1200, 18 USPQ2d 1016 (Fed. Cir.), cert. denied, 502 U.S. 856 (1991), the applicant claimed

erythropoietin (EPO), and every possible analog of the gene (containing about 4000 nucleotides), but only provided the details for preparing only a few EPO analogs and did not provide sufficient disclosure to support the claims. The court found that in view of the structural complexity of the EPO gene, there were manifold possibilities for changes in its structure, and there was uncertainty as to what utility would be possessed by each of the analogs. It was determined that additional disclosure was needed to identify various analogs within the scope of the claim, methods for making them, and structural requirements for producing compounds with EPO-like activity. Here, Applicants admit that the claim genus encompass "numerous structural variants" and also admit that their specification only teaches one example. Furthermore, Applicants do not test any of these structural variants for biological activity, nor do they assert that such molecules possess a common utility (see *Ex parte Bhide* 42 USPQ2d 1441). That is, Applicants have failed to show how to use the vast majority of the claimed compounds.

Finally, the Examiner notes that the Federal Circuit has cautioned against over reliance on the assertion that everything needed to practice the full scope of the claims was known in the art and that a patent need not teach, and preferably omits, what is well known in the art. See *Genentech Inc. v. Novo Nordisk* A/S, 108 F.3d 1361, 1366, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997): "[T]hat general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. ... It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement." Here, Applicants have not provided any utility for the vast number of claimed compounds (see above). In addition, Applicants have not provided a basic

reaction scheme that would enable a person of skill in the art to produce the vast majority of the claimed compounds regardless of whether or not basic organic chemistry principles would permit such a synthesis if it were to be discovered in the future. Thus, these omissions represent more than just "minor" details.

Accordingly, the Enablement rejection cited above is hereby maintained.

Claims Rejections - 35 U.S.C. 102

11. Claims 1, 3, 4, 7, 8 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Singh et al. (Singh, A.; Yao, Q.; Tong, L.; Still, W. C.; Sames, D. "Combinatorial approach to the development of fluorescent sensors for nanomolar aqueous copper" *Tetrahedron Letters* **2000**, *41*, 9601-9605).

For ***claim 1***, Singh et al. (see entire document) disclose fluorescent sensors for aqueous copper ions (e.g., see Singh et al, abstract), which anticipate the claimed invention. For example, Singh et al. disclose a composition comprising a solid resin support (e.g., see page 9603, compound 8 wherein the circle indicates the resin support). Singh et al. also disclose a solid resin support having a multifunctional chemical moiety covalently attached thereto at a resin attachment site (e.g., see page 9603, compound 8 wherein the 1,4,7-triazonane could be considered the multifunctional chemical moiety i.e., each N constituted a different functional group or, in the alternative, the 1,4,7-triazonane (referred to herein as C_6N_3) chemically bonded to the to the ethylamine could be considered the multifunctional chemical moiety (i.e., the $C_6N_3CH_2CH_2N$ portion of the molecule) or, in the alternative, the multifunctional chemical moiety could include the

alkyl amide linkage (i.e., the $C_6N_3CH_2CH_2N(CH_2)_5(C=O)$-portion of the molecule or, in the alternative, the multifunctional chemical moiety could be just the tri-functional $S(=O)2$-NCH_2CH_2N portion of the molecule. In addition, the multifunctional chemical moiety "includes" a hydrophobic anchoring groups (e.g., see page 9603, compound 8 wherein the hydrophobic $-(CH_2)_5-$ anchors the multifunctional group to the solid support or, in the alternative, the hydrophobic $-CH_2-CH_2-$ anchors the C_6N_3 to the solid support or, in the alternative, the $-CH_2-CH_2-$ anchors the multifunctional group to the C_6N_3 copper binding site, etc. Applicants state, "Membrane anchor ... can be any anchoring group that contains alkyl, alkenyl-, alkynyl and polyaromatic chains of carbon containing from about 4 to 30 carbons" (e.g., see specification, page 4, paragraph 1). The $-(CH_2)_5-$ noted above has between "4 to 30" carbons and thus inherently discloses this claimed "anchoring" limitation. Please note that there are many other variations that could read on Applicants' claims (e.g., see also 35 U.S.C. § 112, second paragraph rejection above).

Singh et al. disclose a tri-functional moiety (e.g., see page 9603, compound 8 wherein the C_6N_3 represents the tri-functional moiety possessing three functional nitrogens or, in the alternative the $C_6N_3CH_2CH_2N$ represents the tri-functional moiety possessing two functional C_6N_3 nitrogens and one functional CH_2CH_2N or, in the alternative, the $NCH_2CH_2NS(=O)_2$ represents the tri-functional moiety possessing two functional nitrogens and one functional $(O=)S(=O)$ group or, in the alternative, the $S(=O)_2N(CH_2)_5C(=O)$ represents the tri-functional moiety containing an $S(=O)2$ functional group, a N functional group and a carbonyl functional group. Please note that there are many other variations that could read on Applicants' claims (e.g., see also 35

U.S.C. § 112, second paragraph rejection above).

For ***claims 3-4 and 7-8***, Singh et al. disclose compound 9 wherein the (O=)C-$CH(CH_2CO_2H)$-NH- portion of the multifunctional group represents an aspartic acid "derivative" that contains a carboxyl group that is covalently attached to said resin via the alkyl CH_2 linker.

For ***claim 10***, Singh et al. disclose tentagel resin, which reads on crosslinked polystyrenes (e.g., see figure 1).

Response

12. Applicant's arguments directed to the above 35 U.S.C. § 102 rejection were fully considered (and are incorporated in their entirety herein by reference) but were not deemed persuasive for the following reasons. Please note that the above rejection has been modified from it original version to more clearly address applicants' newly amended and/or added claims and/or arguments.

[1] Applicants argue, "None of the compounds disclosed in Singh anticipate [the claimed invention] ... as none of the Singh compounds contain the membrane anchor limitation" (e.g., see 10/21/05 Response, page 12, paragraph 2).

[2] Applicants argue, "The hydrophobic groups disclosed in Singh ... are introduced post-synthetically ... and are not part of the 'on-resin' assembly taught by the subject application" (e.g., see 10/21/05 Response, page 12, last two paragraphs).

This is not found persuasive for the following reasons:

[1] The Examiner respectfully disagrees. A patent applicant is free to recite features of a claimed limitation either structurally or functionally. *See In re Swinehart*, 439 F.2d 210, 212, 169

USPQ 226, 228 (CCPA 1971) ("[T]here is nothing intrinsically wrong with [defining something by what it does rather than what it is] in drafting patent claims."). Yet, choosing to define an element functionally, i.e., by what it does, carries with it a risk. As stated in *Swinehart*, 439 F.2d at 213, 169 USPQ at 228:

> where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on.

See also *In re Hallman*, 655 F.2d 212, 215, 210 USPQ 609, 611 (CCPA 1981); *In re Ludtke*, 441 F.2d 660, 663-64, 169 USPQ 563, 565-67 (CCPA 1971). Here, Applicants have assumed the risk by setting forth the claimed composition in functional terms (i.e., portions of the molecule "function" as an "anchoring" group). Thus, the rejection is proper because the PTO has reason to believe (see above rejection) that this functional limitation, which was asserted to be critical for establishing novelty in the claimed subject matter (e.g., see 10/21/05 Response, page 12, "The use of a membrane anchoring sidechain ... is novel and unrelated to what is reported by Singh"), is inherently disclosed by Singh (see rejection above). For example, Applicants state, "Membrane anchor ... can be any anchoring group that contains alkyl, alkenyl-, alkynyl and polyaromatic chains of carbon containing from about 4 to 30 carbons" (e.g., see specification, page 4, paragraph 1). Thus, the disclosure of a multi-functional group that contains $-(CH_2)_5-$ group inherently meets this limitation (e.g., see page 9603, compound 8 wherein the hydrophobic $-(CH_2)_5-$ anchors the multifunctional group to the solid support or, in the alternative, the hydrophobic $-CH_2-CH_2-$ anchors the C_6N_3 to the solid support or, in the

alternative, the -CH_2-CH_2- anchors the multifunctional group to the C_6N_3 copper binding site, etc) because this group contains between "4 to 30" carbons and represents an "alkyl" chain.

[2] In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., introduction "pre-" or "post-" synthetically) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). For example, claim 1 does not mention anything about introducing hydrophobic groups pre- or post-synthetically and, as a result, Applicants' arguments are not commensurate in scope with the claims.

Accordingly, the 35 U.S.C. 102 rejection cited above is hereby maintained.

13. Claims 1, 3, 4, 7, 8 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Meienhofer et al. (Meienhofer, J.; Trzeciak, A. "Solid-Phase Synthesis with Attachment of Peptide to Resin through an Amino Acid Side Chain: [8-Lysine]-Vasopressin" *PNAS* **1971**, *68*, 5, 1006-1009).

For ***claim 1***, Meienhofer et al. disclose an O-alkyl containing lysine epsilon coupled to a polystyrene gel (e.g., see Meienhofer et al., page 1006, compound 4), which anticipates the claimed invention. In this scenario, the solid resin is the standard Merrifeld Resin (e.g., see page 1006, column 2, first full paragraph; see also compound 1) and the multifunctional chemical moiety is a lysine amino acid containing an R' O-alkyl hydrophobic anchoring group. Please note that the hydrophobic anchoring group

could also be the t-butyl portion of the Boc group and/or the any of the hydrophobic portions of the vasopressin peptide (e.g., the phenylalanine, tyrosine side chains), which would allow it to "anchor" to its hormonal receptors in the cell membrane. Meienhofer et al. disclose the trifunctional lysine wherein the ϵ-NH, α-NH and CO represent the three functional groups (e.g., see page 1006, compound 4).

For ***claim 3-4***, Meienhofer et al. disclose a lysine amino acid derivative and a -$(CH_2)_4$- side chain and a reactive arm that contains a CO_2H or a -NH_2 after deprotection of the R' and Boc, groups respectively (e.g., see figure 4). The ϵ-NH might also be considered to be a reactive group (e.g., see 35 U.S.C. 112, second paragraph rejection, above).

For ***claim 7***, Meienhofer et al. disclose both a reactive arm that contains a CO_2H or a -NH_2 after deprotection of the R' and Boc, groups respectively (e.g., see figure 4).

For ***claim 8***, Meienhofer et al. disclose lysine (e.g., see figure 4).

For ***claim 10***, Meienhofer et al. disclose Merrifield resin i.e., chloromethyl polystyrene-2% divinylbenzene (e.g., see page 1006, column 2, second full paragraph).

Response

14. Applicant's arguments directed to the above 35 U.S.C. § 102 rejection were fully considered (and are incorporated in their entirety herein by reference) but were not deemed persuasive for the following reasons. Please note that the above rejection has been modified from it original version to more clearly address applicants' newly amended and/or added claims and/or arguments.

[1] Applicants argue, "None of the compounds disclosed in Meienhofer anticipate [the claimed invention] ... as none of the Meienhofer compounds contain the membrane anchor limitation" (e.g., see 10/21/05 Response, page 13).

[2] Applicants argue, "The hydrophobic groups disclosed in Meienhofer ... are introduced post-synthetically ... and are not part of the 'on-resin' assembly" (e.g., see 10/21/05 Response, page 13).

This is not found persuasive for the following reasons:

[1] The Examiner respectfully disagrees. A patent applicant is free to recite features of a claimed limitation either structurally or functionally. *See In re Swinehart*, 439 F.2d 210, 212, 169 USPQ 226, 228 (CCPA 1971) ("[T]here is nothing intrinsically wrong with [defining something by what it does rather than what it is] in drafting patent claims."). Yet, choosing to define an element functionally, i.e., by what it does, carries with it a risk. As stated in *Swinehart*, 439 F.2d at 213, 169 USPQ at 228:

> where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on.

See also *In re Hallman*, 655 F.2d 212, 215, 210 USPQ 609, 611 (CCPA 1981); *In re Ludtke*, 441 F.2d 660, 663-64, 169 USPQ 563, 565-67 (CCPA 1971). Here, Applicants have assumed the risk by setting forth the claimed composition in functional terms (i.e., portions of the molecule "function" as an "anchoring" group). Thus, the rejection is proper because the PTO has reason to believe (see above rejection) that this functional limitation, which was asserted to be critical for establishing novelty in the claimed subject matter (e.g., see 10/21/05 Response,

page 13, "The importance of the membrane anchor for the presentation of ligands on membranes ... is clearly stated in the application"), is inherently disclosed by Meienhofer (see rejection above). For example, Applicants state, "Membrane anchor ... can be any anchoring group that contains alkyl, alkenyl-, alkynyl and polyaromatic chains of carbon containing from about 4 to 30 carbons" (e.g., see specification, page 4, paragraph 1). Thus, the disclosure of a t-boc group, for example, inherently anticipates the claim because this group contains between "4 to 30" carbons and represents an "alkyl" chain (e.g., see above rejection describing t-boc and o-alkyl chains)

[2] In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., introduction "pre-" or "post-" synthetically) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). For example, claim 1 does not mention anything about introducing hydrophobic groups pre- or post-synthetically and, as a result, Applicants' arguments are not commensurate in scope with the claims.

Accordingly, the 35 U.S.C. 102 rejection cited above is hereby maintained.

New Objections/Rejections

Specification

15. The specification is objected to because it contains a new "incorporation by reference" paragraph that was added after the filing date (e.g., see 10/21/05 Amendment). An

incorporation-by-reference statement added after the filing date of an application is not permitted because no new matter can be added to an application after its filing date. See 35 U.S.C. § 132(a).

Claims Rejections - 35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 1, 3, 4, 7, 8 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Filippusson et al. (Filippusson et al. "Design, synthesis and evaluation of biomimetic affinity ligands for elastases" *J. Mol. Recognit.* **2000**, *13*, 370–381) as evidenced by March et al. (March, J.; Smith, M. B. Advanced Organic Chemistry Fifth Edition. New York: John Wiley and Sons, Inc. **2001**, pages 532 and 533).

For ***claim 1***, Filippusson et al. (see entire document) disclose various trifunctional triazine linker compositions with solid-phase supports used in combinatorial synthesis (e.g., see Filippusson et al., abstract; see also figure 2; see also Materials and Methods; see also figure 1), which anticipates the claimed invention. For example, Filippusson et al. disclose a solid resin support (e.g., see figure 2, wavy line; see also Materials and Methods section wherein Cross-linked agarose (Sepharose CL-6B 200) is disclosed). Filippusson et al. further disclose a trifunctional chemical moiety covalently attached thereto at a resin attachment site (e.g., see figure 2 wherein the resin attachment site is

indicated by the wavy line). In this scenario, the three functionalities are the solid phase linker (NH-CH(-OH)-CH_2-CH_2-O), R_1NH and R_2NH (or Cl) (e.g., see figure 2). Finally, Filippusson et al. disclose the use of a hydrophobic membrane anchoring group as one functionality thereon (e.g., see figure 1 wherein pentylamine is disclosed as one of the R1 groups). Applicants state, "Membrane anchor ... can be any anchoring group that contains alkyl, alkenyl-, alkynyl and polyaromatic chains of carbon containing from about 4 to 30 carbons" (e.g., see specification, page 4, paragraph 1). Thus, pentylamine, an alkyl with 5 carbons, falls within the scope of this definition.

For ***claims 3 and 4***, Filippusson et al. disclose the amino acid derivatives alanine, alanyl-alanine, tryptamine, 5-hydroxyl-tryptamine (e.g., see figure 1), which include amino, hydroxyl and carboxyl groups.

For ***claim 7***, Filippusson et al. disclose a reactive arm group that is a carboxyl group covalently attached to said resin attachment site (e.g., see disclosing 4-(butylamino)benzoic acid, alanine, alanyl-alanine; see also figure 2).

For ***claim 8***, Filippusson et al. disclose alanine, a "derivative" of serine (e.g., see March et al., pages 531 and 532, section 10-88 showing that that alkyl groups like the CH_2SH side chain of serine can undergo a desulfurization reaction to convert it into the CH_3 group of alanine)

For ***claim 10***, Filippusson et al. disclose, for example, cross-linked agarose (e.g., see figure 2; see also Materials and Methods section wherein Cross-linked agarose (Sepharose CL-6B 200) is disclosed), which qualifies natural polymer.

Conclusion

Applicant's amendment necessitated any new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon D. Epperson, Ph.D.
March 31, 2006